



Legal Certainty of Implementing Telemedicine Services in Indonesia as Effort Towards Renewal of National Health Law

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Abstract

Digital health services are carried out without direct interaction between doctors and patients, where patients only need to consult with doctors in virtual rooms, such as through electronic media and social media, known as Telemedicine. Apart from the hope that telemedicine promises various conveniences and opportunities so that it can be used as a solution in overcoming health problems, it is also realized that telemedicine brings potential legal problems in medical practice. Many of the legal implications of medicolegal telemedicine. Other important aspects are the doctor-patient relationship, standard of care and informed consent. The formulation of the problem that will be raised in this study, namely: First, how is the legal certainty of the regulation of telemedicine services in terms of the laws and regulations in the field of health law in Indonesia? and Second, what is the concept of the right telemedicine regulation in the provision of health services based on the principle of legal certainty in Indonesia? The purpose of this research is to find out the legal certainty regarding the regulation of telemedicine services in Indonesia, and to find out the concept of the right telemedicine regulation based on the principle of legal certainty in Indonesia. The research method in writing this proposal uses a normative juridical approach. The result of this research is that legal certainty is needed to regulate telemedicine. There is no specific law that regulates telemedicine, and without legal certainty this will certainly have an impact on legal protection.

I. Introduction

The world's increasingly rapid technological advances have provided all conveniences for humans in various aspects of life, including in the health sector. Mastery of science and technology (science and technology) in all sectors is increasingly widespread and globalization has contributed to this increasingly complex influence in all fields, including health science and technology such as telemedicine.¹

¹ Arief B. Witarto, "Freedom and Ethics of Science," *Bisnis Indonesia Daily*, 2012.

The 1945 Constitution stipulates that everyone has the right to live and has the right to defend his/her life and live, every child has the right to survival, growth and development; Everyone has the right to develop themselves through the fulfillment of their basic needs, in order to improve the quality of their life, everyone has the right to live in physical and spiritual prosperity, to live and to have a good and healthy environment and to have the right to health services; The state is responsible for providing health care facilities. Article 34 Paragraph (3) Fourth Amendment to the 1945 Constitution states that the State has the responsibility for the provision of adequate health care facilities and public service facilities for the community.

Health (medical) services are important things that must be maintained or improved in accordance with applicable service standards, so that people can feel the services provided. Service itself is essentially an effort to help prepare everything that other people need and can provide satisfaction in accordance with the wishes expected by consumers. There are three components involved in a service process, namely, service is largely determined by the quality of service provided, who performs the service, and consumers who judge a service through the expectations they want.²

In order to prevent the spread of Covid-19, one of which is in face-to-face health services, it is necessary to carry out restrictions. This means that health services must be carried out through telemedicine, namely through Circular Letter number HK.02.01/MENKES/303/2020 concerning the Implementation of Health Services through the Utilization of Information and Communication Technology in the Context of Preventing the Spread of Covid-19, dated April 29, 2020. In the Circular, it is explained that Health services are provided through telemedicine. The circular letter is addressed to all Heads of Provincial and Regency/City Health Offices, the General Chairperson of the Indonesian Doctors Association (PB IDI), the General Chairperson of the Indonesian Dentist Association (PB PDGI), and the General Chairperson of the Indonesian Pharmacists Association (PP. IAI) throughout Indonesia³ so that this condition encourages the very rapid development of the birth of long-distance health services or better known as Telemedicine. Telemedicine, comes from the word "tele" which means "distance", and "medical" which means "medical". Collectively, telemedical services mean "services that use electronic communication facilities to provide medical services or support remotely (not face-to-face)".⁴

Telemedicine is a long-distance health service carried out by health professionals using information and communication technology, and this is also expected to include the

² Titik Triwulan and Shinta Febrian, "Legal Protection for Patient," *Jakarta: Prestasi Pustaka*, 2010, 48.

³ Institute of Medicine, "Preventing the Spread of Covid-19, Health Services Are Performed Through Telemedicine," accessed July 15, 2021, <https://lspkesehatan.kemkes.go.id/berita/detail/Cegah-Penyebaran-Covid-19-Pelayanan-Kesehatan-Dilakukan-Melalui-Telemedicine-Fo0a4>.

⁴ Daniel R Masys, "Telemedicine: A Guide to Assessing Telecommunications in Health Care" (BMJ Group BMA House, Tavistock Square, London, WC1H 9JR, 1997).

exchange of information for diagnosis, treatment, prevention of injury and research as well as evaluation of this education in accordance with Regulation of the Minister of Health Number 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Service Facilities.⁵ Consultation to establish diagnosis, therapy, and/or disease prevention is the object of Telemedicine Service Implementation. Apart from the hope that telemedicine promises various conveniences and opportunities so that it can be used as a solution in overcoming health problems, it is also realized that telemedicine brings potential legal problems in medical practice.

According to Gorea R.K, there are many legal implications of medicolegal telemedicine such as relating to registration, licensing, insurance, privacy quality, and confidentiality issues, as well as other risks associated with electronic health care communications. Other important aspects are the patient-physician relationship, standard of care and informed consent.⁶ This is also compounded by the contradictory situation between medical ethics and the commercialization of existing medical services, so the possibility of medical service capitalism in Indonesia is not impossible to overshadow or even have penetrated the telemedicine medical service network in Indonesia. The influx of foreign investment in the health sector in Indonesia will have an effect and will add to the complexity and complexity of health care in Indonesia. To prevent this, it is necessary to have political support from the government and legislators who are able to keep up with the pace of multinational health corporations. Maintaining the balance of this pace is a very important matter but also not easy because global corporations are the owners of patents for their technology.⁷

Telemedical services have the potential to provide quick, easy, and inexpensive medical triage services, which can direct emergency patients to the nearest hospital, call an ambulance, or simply refer patients to the right specialist based on their symptoms. Another classic example is the depression prevention service that aims to prevent suicide, which also exists in the United States and some developed countries but does not yet exist in Indonesia. In this modern era, certain programs are increasingly appearing that offer consultation on health problems via the internet or mobile phone applications. This type is widely developed in the world, including Indonesia. Even though it started with good intentions and goals, this type of telemedical service is prone to ethical problems, including the doctor's professional

⁵ Hammam Riza, "Improving Health Services During a Pandemic, BPPT Supports the Utilization of Telemedicine, in an Acceleration Webinar on the Utilization of Telemedicine for Health Services during the Covid-19 Pandemic," 2020, <https://www.bppt.go.id/layanan-informasi-publik/4134-tingatkan-layanan-kesehatan-di-masa-pandemi-bppt-dukungan-pemanfaatan-telemedicine>.

⁶ Rakesh Gorea, "Legal Aspects of Telemedicine: Telemedical Jurisprudence," *Journal of Punjab Academy of Forensic Medicine & Toxicology* 5, no. 3 (2005).

⁷ Arman Anwar, "Prinsip Tanggung Gugat Dalam Praktik Kedokteran Telemedicine" (Universitas Airlangga, 2015).

confidence in the limited information on the patient's condition, differences in the expectations of doctors and patients, and confidentiality issues.⁸

Another possible confidentiality issue is the case with telemedical services between doctors and doctors, namely, a stranger overhearing a telemedicine telephone conversation or accidentally stealing a look from behind a patient during a consultation via the chat/forum feature. The difference is that telemedicine staff and doctors are experienced personnel who have been warned about patient confidentiality, even for doctors listed in KODEKI, while patients are ordinary people who may not pay attention to this. In addition, these irresponsible people will immediately know who the patient referred to in the consultation is, of course the person they stole saw/heard. Patients should always try to prevent this possibility, for example by consulting only in a closed and private place. Furthermore, hacking the confidentiality of patient data including text, audio and visual/video data is one of the main risks of telemedicine systems. This is very necessary to pay attention to, especially if there are sensitive patient data that would be very detrimental if published, such as a history of sexually transmitted diseases and mental disorders. The security of this confidential data should be maintained as much as possible, for example by ensuring the doctor being consulted is in a place that can maintain confidentiality (such as in a private room) when using a telephone, to prevent people from eavesdropping, or when it is done using a chat application via a smart phone. , should use applications that have a good reputation in terms of confidentiality and prevent people from stealing views.⁹

Based on the description that the author has described above, it can be concluded that telemedical services provide an opportunity to carry out medical practices that are free from distance restrictions, but have the potential to cause problems because the online diagnosis process by doctors is carried out in the absence of face-to-face meetings between doctors and patients, doctors do not perform a physical history before making a diagnosis, so that it does not rule out the possibility of misdiagnosis of the patient. If this error occurs, of course the injured patient needs to get legal protection in the form of the doctor's responsibility. Telemedical services as part of technological progress are indeed disruptive, therefore regulations are needed to ensure the development of telemedical services in accordance with the goals and noble values of medical ethics based on KODEKI and the Doctor's Oath. The government, IDI, and MKEK are expected to support and oversee the development of this telemedical service in a good direction and cooperate with each other in the audit and evaluation of telemedical services in Indonesia. This condition becomes the central point and becomes the main problem in this research proposal, so that legal certainty in the implementation of

⁸ Widyawati, "Alur Mendapatkan Layanan Telemedicine Bagi Pasien Isolasi Mandiri - Sehat Negeriku," accessed July 15, 2021, <https://sehatnegeriku.kemkes.go.id/baca/berita-utama/20210707/5338052/alur-mendapatkan-layanan-telemedicine-bagi-pasien-isolasi-mandiri/>.

⁹ Ibid.

telemedicine services can be implemented properly, and in line with the objectives of health services.

By referring to the background of the problem above, it can be stated that the formulation of the problem that will be raised in this study, namely First, How is legal certainty regarding the regulation of telemedicine services in terms of legislation in the field of health law in Indonesia? Second, how is the concept of the right telemedicine arrangement in providing health services based on the principle of legal certainty in Indonesia? Previous research on telemedicine, among others, by Abigail Prasetyo and Dyah Hapsari Prananingrum, with an article entitled Disruption of Telemedicine-Based Health Services: Legal Relations and Legal Responsibilities of Patients and Physicians,¹⁰ which explains legal relations and legal responsibilities in telemedicine. Meanwhile, this research analyzes the concept of telemedicine regulation in Indonesia

2. Research Method

The method of approach in this writing is a normative juridical research. Normative juridical research is legal research carried out by researching and reviewing library materials.¹¹ In this study, researchers will carry out a conceptual approach, a statute approach and a comparative approach. Synchronization of laws and regulations, both vertically and horizontally in analyzing legal certainty in the implementation of telemedicine health services in Indonesia. Researchers also take a comparative or comparative approach as a means to examine telemedicine arrangements in several countries, so that they can understand the similarities and differences regarding the development and improvement of legal provisions for telemedicine services in Indonesia.

3. Results and Discussions

3.1 Legal Certainty in the Regulation of the Implementation of Telemedicine Services in View from the Legislation in the Field of Health Law in Indonesia **Legal Certainty in the Regulation of the Implementation of Telemedicine Services in View from the Legislation in the Field of Health Law in Indonesia**

Article 28A of the 1945 Constitution states that everyone has the right to live and has the right to defend his life and live, followed up in Article 28J of the 1945 Constitution which emphasizes that everyone is obliged to respect the human rights of others, and in exercising their rights and freedoms, everyone is obliged to comply with the restrictions set forth by constitution. This is the basic right that underlies the right of a patient to get the best health care for himself. The right to health is affirmed in Article 28H Paragraph (1) of the 1945 Constitution which states that everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy living environment and the right to health services. As a provision for its

¹⁰ Abigail Prasetyo and Dyah Hapsari Prananingrum, "Disrupsi Layanan Kesehatan Berbasis Telemedicine: Hubungan Hukum Dan Tanggung Jawab Hukum Pasien Dan Dokter," *Refleksi Hukum: Jurnal Ilmu Hukum* 6, no. 2 (2022): 225–46.

¹¹ Soerjono Soekanto and Sri Mamudji, *Penelitian Hukum Normatif* (Jakarta: Rajawali Press, 1985).

implementation, contained in the explanation of Law Number 36 of 2009 concerning Health (hereinafter referred to as the Health Law), Indonesia recognizes that health is a human right and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the 1945 Constitution.¹²

Health services are the object of consent for treatment and care. Efforts to improve the quality of human life in the health sector are a very broad and comprehensive effort, these efforts include improving public health, both physical and non-physical. In the National Health System it is stated that health concerns all aspects of life whose scope and range is very broad and complex.¹³ The National Health System is the form and method of implementing health development that combines the various efforts of the Indonesian people in one step in order to achieve the goals of health development within the framework of realizing people's welfare as referred to in the 1945 Constitution.¹⁴ The role of health law in achieving the goals of the National Health System is the realization of a health legal system that refers to the development of legal substance, legal culture as well as the development of health legal apparatus.

Initially, Telemedicine was aimed at developing health services for people in remote areas. This can be seen in Article 15 of the Minister of Health Regulation Number 90 of 2015 concerning the Implementation of Health Services in Remote and Very Remote Area Health Service Facilities which states that the development of health service patterns in health service facilities in remote and very remote areas, one of which is carried out by telemedicine-based health services. Whereas Article 19 of the Minister of Health Number 90 of 2015 states that telemedicine-based health services as referred to in Article 15 letter d aim to provide benefits in increasing the accuracy and speed of medical diagnosis and medical consultation at first-level health care facilities and advanced level referral levels that do not have certain health workers.¹⁵

Telemedicine regulation in Indonesia is technically regulated in the Regulation of the Minister of Health of the Republic of Indonesia. When compared to several other countries, such as Malaysia and India, these two countries already have special laws governing Telemedicine. Malaysia has had the Telemedicine Act 1997, India has the Telemedicine Act 2003, and California USA has the Telehealth Advancement Act of 2011.

Telemedicine is an alternative choice for economical and practical considerations because patients do not have to come to the hospital and meet physically. But this does not answer the needs of patients in real medical services. Good health services include holistic and comprehensive care, namely: covering the patient's entire physical and spiritual body (whole body system) including nutrition, not only organ oriented but patient and family oriented and views humans as bio-psychosocial beings in their

¹² Eka Julianta Wahjoepramono, *Konsekuensi Hukum Dalam Profesi Medik* (Bandung: Karya Putra Darwati, 2012).

¹³ Bahder Johan Nasution, "Doctor's Liability Health Law," *Jakarta, Rineka Cipta*, 2005.

¹⁴ Yustina Hartini and Sulasmono, "Apotek Ulasan Beserta Naskah Peraturan Perundang-Undangan Terkait Apotek," *Yogyakarta: Universitas Sanata Dharma*, 2006.

¹⁵ Yovita Arie Mangesti, "Konstruksi Hukum Transformasi Digital Telemedicine Di Bidang Industri Kesehatan Berbasis Nilai Pancasila" (Prosiding Seminar Nasional & Call for Papers Hukum dan Industri, 2019).

ecosystem. Comprehensive means not only curative but also prevention-oriented including health promotion, specific protection (primary), early case detection, prompt treatment (secondary) and disability limitation/rehabilitation (tertiary).¹⁶

Conventional medical services are indeed in a diametrical position with telemedicine. In telemedicine, the patient will assume that the doctor is a great and competent person because he can treat from afar without the need for a supporting diagnosis. This success is closely correlated with whether the patient can describe in detail the symptoms or pain he is suffering from, or whether he can take photos of the physical symptoms of pain, which of course cannot be ascertained with accuracy. This will obscure the identity of medical practice which is based on human values and justice.¹⁷

3.1.1 Telemedicine in Medical Practice Act

In Article 35 Paragraph (1) of the Medical Practice Act, the authorized doctor is a doctor who has a Registration Certificate (STR). On the basis of STR, doctors have the authority to practice medicine in accordance with their education and competencies, which consist of: interviewing patients; examine the patient's physical and mental; determine the supporting examination; establish a diagnosis; determine the management and treatment of patients; perform medical or dental procedures; write prescriptions for drugs and medical devices; issue a doctor's or dentist's certificate; store drugs in permitted quantities and types; and dispensing and dispensing drugs to patients, for those who practice in remote areas where there are no pharmacies. There are 10 kinds of doctor's authority, which, if examined carefully, are overlooked in telemedicine, especially in establishing a diagnosis.¹⁸

The steps in establishing a diagnosis are history/anamnesis taking, physical examination, supporting examination and diagnosis, so the factors that influence misdiagnosis can be started with a wrong history. A doctor will be able to direct the possibility of diagnosis in a patient through a good history. A good history must refer to systematic questions, which are guided by four main points (The Fundamental Four) which include: History of Present Disease (RPS), History of Past Diseases (RPD), Family Health History, Social and Economic History; and Seven Pearls of History (The Sacred Seven), namely the allocation of complaints, quality, quantity, time (onset, duration, frequency, and chronology), aggravating factors, mitigating factors, and accompanying complaints.¹⁹

With regard to paragraphs (1), (2), (3) of Article 36 of the Medical Practice Act, it means that the authority of a doctor is only given to practice in one to three places, of course with a clear domicile. The law does not mention the world of the internet. This article cannot necessarily be interpreted that at the domicile it is possible to carry out therapeutic contract transactions via the internet. The requirements of the next article are clear, that the law has not provided protection for telemedicine. A place that is

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

protected as a place to practice medicine is a real place, a domicile address, not a domain on the internet.²⁰

The legal problems above certainly cause legal uncertainty in therapeutic contract transactions via the internet. The place referred to in the Medical Practice Act is a place to practice medicine is a real place, domicile address, not a domain on the internet. Analyzed based on the theory of legal certainty, in the formation of the rule of law, the main principle is built in order to create a clarity on the rule of law, this principle is legal certainty. Legal certainty is one of the goals of the rule of law. This view was expressed by Radbruch and Kusumaatmadja.²¹

Normative legal certainty is when a regulation is made and promulgated with certainty because it regulates clearly and logically. It is clear in the sense that it does not cause doubt (multi-interpretation) and is logical. It is clear in the sense that it becomes a system of norms with other norms so that they do not clash or cause conflicting norms.²² Associated with the above problems, there has been a legal uncertainty in the regulation of telemedicine. The Medical Practice Act has not regulated the implementation of telemedicine in Indonesia, and without legal certainty this will certainly have an impact on legal protection, both legal protection for doctors and legal protection for patients.

3.1.2 Telemedicine in the Study of Information and Electronic Transaction Act

Article 3 of Act Number 11 of 2008 concerning Information and Electronic Transactions in conjunction with Act Number 19 of 2016 concerning Amendments to Act Number 11 of 2008 concerning Electronic Information and Transactions (hereinafter referred to as the Act on Electronic Information and Transactions) states that Utilization of Information Technology and Electronic Transactions is carried out based on the principles of legal certainty, benefit, prudence, good faith, and freedom to choose technology or be technology neutral. Article 5 of the Electronic Information and Transactions Act states that Electronic Information and/or Electronic Documents and/or their printouts are legal evidence. Electronic Information and/or Electronic Documents and/or their printouts are extensions of legal evidence in accordance with procedural law in force in Indonesia.

Associated with efforts to resolve medical disputes, in terms of the position of legal evidence²³ telemedicine documentation carried out via smart phones and disaptures, photographs, recordings, are only located as instructions, in contrast to medical record documents in the health service unit. The strength of evidence from the evidence of instructions and official letters is also different. In line with this development, regulations are needed that regulate telemedicine evidence.

3.1.3 Telemedicine in Health Act

²⁰ Ibid.

²¹ Mochtar Kusumaatmadja, "Konsep-Konsep Pembangunan Hukum Dalam Pembangunan," *Bandung, Alumni*, 2002.

²² R Tony Prayogo, "Penerapan Asas Kepastian Hukum Dalam Peraturan Mahkamah Agung Nomor 1 Tahun 2011 Tentang Hak Uji Materiil Dan Dalam Peraturan Mahkamah Konstitusi Nomor 06/Pmk/2005 Tentang Pedoman Beracara Dalam Pengujian Undang-Undang," *Jurnal Legislasi Indonesia* 13, no. 2 (2016): 191-201.

²³ Endang Wahyati Yustina, *Mengenal Hukum Rumah Sakit* (CV Keni Media, 2012).

Article 42 of Act Number 36 of 2009 concerning Health confirms that technology and health technology products are procured, researched, circulated, developed, and utilized for public health. Health technology includes all methods and tools used to prevent disease, detect disease, relieve suffering from disease, cure, minimize complications, and restore health after illness. What is meant by "health technology" in this provision is a method, method, process, or product resulting from the application and utilization of scientific disciplines in the health sector that generate value for the fulfillment of needs, continuity, and improvement of the quality of human life. The phrase "all methods" indicates that this Health Law opens up opportunities for the implementation of Indonesian telemedicine, but it is not explicitly stated in the editorial article of the Act.

3.1.4 Comparative Study of Arrangements for the Implementation of Telemedicine Services in Several Countries

Indonesia is relatively late in implementing telemedicine technology, even though the potential use of information and communication technology (ICT) has been recognized by WHO in 2005. Therefore, the ethical and legal impacts of telemedicine technology have not been widely explored by regulators. For example, Telemedicine, which is still relatively new in Indonesia, is not supported by related regulations, even though this regulation is very important. Not only to provide legal certainty to telemedicine service providers, but also to protect patients and the general public who use these technology services. Regulations that ratify the use of Telemedicine technology have only been enacted through the Minister of Health in 2019. Even though several countries have explored the use of Telemedicine since the 1990s. Health Service Facilities (Fasyankes) who wish to take advantage of Telemedicine services cannot underestimate the ethical and legal aspects. In addition to having to comply with existing regulations, Health Facilities must also maintain patient trust so that they do not hesitate to take advantage of the Telemedicine services that have been provided.²⁴ The following will discuss a comparative study of telemedicine settings in several countries:

a. Malaysia

Malaysia already has a package of laws relating to cyberlaw such as the Telemedicine Act, Communication and Multimedia Act, and the Digital Signature Act. The establishment of cyberlaw in Malaysia was previously preceded by government policy by establishing the MSC (Malaysia Super Corridor). That is, the government's initiative becomes a benchmark in the development of information technology. Malaysian Law 564 Telemedicine Act 1997 is the Act to regulate and control the practice of telemedicine; and for matters related to it. According to this Law, Telemedicine means the practice of medicine using audio, visual and data communications. Based on this law, parties who can practice telemedicine are determined, namely:

- (1) *Persons who may practise telemedicine, No person other than –*
 - (a) *a fully registered medical practitioner holding a valid practising certificate; or*
 - (b) *a medical practitioner who is registered or licensed outside Malaysia and –*

²⁴ Lintasarta, "Bagaimana Masa Depan Telemedicine Pasca-Pandemi?," Lintasarta, 2021, <https://blog.lintasarta.net/article/solution/smart-city/telemedicine//bagaimana-masa-depan-telemedicine-pasca-pandemi>.

- (i) *holds a certificate to practise telemedicine issued by the Council; and*
 - (ii) *practises telemedicine from outside Malaysia through a fully registered medical practitioner holding a valid practising certificate, may practise telemedicine.*
- (2) *Notwithstanding paragraph (1)(a) the Director General may, upon an application being made by a fully registered medical practitioner, permit in writing, subject to such terms and conditions as the Director General may specify, a provisionally registered medical practitioner, a registered medical assistant, a registered nurse, a registered midwife or any other person providing healthcare, to practise telemedicine if such person –*
- (a) *is deemed suitable by the Director General to be so permitted; and*
 - (b) *is under the supervision, direction and authority of the fully registered medical practitioner making the application.*
- (3) *Any person who practises telemedicine in contravention of this section, notwithstanding that he so practises from outside Malaysia, shall be guilty of an offence and shall on conviction be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding five years or to both."*

Based on the article above, the parties who can practice telemedicine based on the Telemedicine Act 1997 Act 564 are:

- 1) A medical practitioner who is registered and has a valid practice certificate; or
- 2) A medical practitioner registered or licensed outside Malaysia, for which the medical practitioner has a certificate to practice telemedicine issued by the Malaysian Medical Council; and who practice telemedicine from outside Malaysia through a registered medical practitioner who has a valid practice certificate, can practice telemedicine.

In addition to the above parties, the Director General of Health Malaysia may (on request made by a fully registered medical practitioner) authorize in writing, subject to the terms and conditions set by the Director General, a temporary registered medical practitioner, medical assistant registered nurse, registered nurse, registered midwife or other person providing health care, to practice telemedicine if the person deems fit by the Director General of Health Malaysia to be permitted, and under the supervision, direction and authority of the registered medical practitioner making the application. If the practice of telemedicine is contrary to this provision, even though it is also practiced from outside Malaysia, it will be found guilty of committing an offense and will be subject to a maximum fine of five hundred thousand ringgit and/or a maximum imprisonment of five years.

The Telemedicine Act 1997 Act 564 also stipulates certain methods or forms and documents, information and costs required for an Application for a certificate of telemedical practice that must be made by a registered or licensed medical practitioner outside Malaysia through a medical practitioner who registered with the Malaysian Medical Council. The Malaysian Medical Council issues a certificate to practice telemedicine issuing to the applicant a certificate for a maximum period of three years subject to the terms and conditions specified by the Malaysian Medical Council in the certificate.

The Malaysian Medical Council may at any time cancel the issued certificate of telemedical practice, if the certificate holder is issued in violation of the terms or conditions specified in the certificate. With regard to the cancellation, or the refusal of the Malaysian Medical Council to issue or cancel the certificate, there are steps that can be taken by those who feel aggrieved as a result of the Malaysian Medical Council's decision²⁵ which can file an appeal to the Minister whose decision is final.

In the Telemedicine Act 1997 Act 564 also requires consent that must be given by the patient before carrying out this telemedicine practice, and that consent must be stated in writing. This is expressly stated in Article 5 Paragraph 1 Telemedicine Act 1997 Act 564, as follows:

“Before a fully registered medical practitioner practises telemedicine in relation to a patient, the fully registered medical practitioner shall obtain the written consent of the patient.”

And as is usually an agreement in medicine, there are several things that need to be informed to the patient, before the patient gives his consent. Based on Article 5 Paragraph (2) of the Telemedicine Act 1997 Act 564, things that must be conveyed to the patient before the patient gives his consent are:

- 1) The patient is free to withdraw his consent at any time without affecting his right to future care or treatment;
- 2) Potential risks, consequences and benefits of telemedicine
- 3) That all existing confidentiality safeguards remain in place for any information about a patient obtained or disclosed during telemedicine interactions
- 4) Any images or information communicated or used during or resulting from telemedicine interactions that can be identified as, on, or about the patient will not be shared with researchers or any other person without the patient's consent.

Consent given by the patient is an agreement that contains a statement signed by the patient, which indicates that he understands the above information, this information has been discussed with a registered medical practitioner. In this Act it is also stated that the Minister may make regulations that are deemed necessary to implement the provisions of this Act, including provisions regarding:²⁶

- 1) To set minimum standards with respect to any facilities, computers, apparatus, tools, equipment, instruments, materials, goods and materials to be used in the practice of telemedicine in any place;
- 2) To provide acceptable quality assurance and quality control with respect to telemedicine services;
- 3) To require persons practicing telemedicine to maintain such books, records and reports as may be necessary for the proper enforcement and

²⁵ “Malaysian Medical Council Decision Regarding Rejection or Cancellation of Certificate of Telemedicine Practice.”

²⁶ Article 6 Paragraph (2) Malaysia Telemedicine Act 1997 Act 564

administration of this Act and to determine the manner in which such books, records and reports are kept and published;

- 4) To request the provision of statistical information to the Director General;
- 5) To stipulate that the violation of any provision of any regulation made under this Act constitutes an offence, and that persons convicted of such offense shall be subject to a fine or imprisonment or both but the fine shall not exceed five thousand ringgit and imprisonment of not more than one year;
- 6) To determine other matters required or permitted by this Act to determine.

Based on the description above, the implementation of telemedicine in Malaysia is regulated in an Act and technical implementation is followed up in a Ministerial Regulation.

b. India

India being a very large country which is densely populated, so telemedicine plays a very important role in enabling medical services to be made accessible and delivered to remote areas as well, moreover as concentration of medical healthcare facilities is found more in cities than in rural India, which make up the majority of the national population. India has the Telemedicine Act 2003.

ISRO (Indian Space Research Organization) made humble beginnings in telemedicine in India with the Telemedicine Pilot Project in 2001, linking Apollo Chennai Hospital with Apollo Rural Hospital in Aragonda village in Chittoor district of Andhra Pradesh.²⁷ The development of telemedicine facilities in India is largely due to the joint efforts of ISRO, Department of Information Technology, Ministry of Foreign Affairs, Ministry of Health and Family Welfare combined with the State Government. This telemedicine network has covered and connected 45 remote and rural hospitals (such as Andaman and Nicobar islands and Lakshwadeep, hilly areas of Jammu & Kashmir, Medical College Hospital in Orissa among other rural hospitals) and 15 super specialty hospitals.²⁸ Telemedicine is one of the successful fields in India where the private sector is taking the initiative and has been acting actively for public health management. Some of India's private sectors in telemedicine include Narayana Hrudayalaya, Apollo Telemedicine Enterprises, Asia Heart Foundation, Escorts Heart Institute, Amrita Institute of Medical Sciences and Aravind Eye Care.²⁹

In India, telemedicine services are under the jurisdiction of the Ministry of Health and Family Welfare and the Department of Information Technology. Telemedicine has also been extended to traditional medicine in India, such as the National Rural Ayush Telemedicine Network which aims to promote the benefits of traditional healing methods to the wider community using telecommunications media. Prior to 2020, there was little concern about the practice of telemedicine largely due to the lack of existing guidelines and ambiguity. In the case of *Deepa Sanjeev Pawaskar & Anr. Vs*

²⁷ ISRO Telemedicine Initiative, "Telemedicine & Law – An Indian Perspective | IIPRD Blog - Intellectual Property Discussions," accessed December 1, 2021, <https://iiprd.wordpress.com/2020/05/13/telemedicine-law-an-indian-perspective/>.

²⁸ Ibid.

²⁹ Kedar G Mehta and P Chavda, "Telemedicine: A Boon and the Promise to Rural India," *J Rev Prog* 1, no. 6 (2013): 1-3.

Maharashtra State, Bombay High Court refused to provide anticipatory bail to 2 doctors involved in the treatment of a patient who eventually died and the husband filed criminal charges against the doctors accusing them of criminal negligence. The case also involved the use of telecommunications as a medium of consultation. As there is no law in India that regulates the practice of telemedicine consulting, the assessment has led to medical bodies repeatedly petitioning the Medical Council of India and the government to issue clear guidelines for regulating Telemedicine.³⁰

To deal with the crisis facing the country and the need to enforce social distancing and eliminate unnecessary movement of patients to clinics/hospitals, on 25 March 2020 Ministry of Health and Family Welfare, Government of India issued Telemedicine Practice Guidelines, 2020 prepared in partnership with NITI Aayog (Also called "National Institute for India's Transformation" - which is the main policy 'Think Tank' of the Government of India, providing direction and policy advice).³¹ The provisions related to these guidelines are briefly as follows :³²

- 1) Guideline No. 1.1.1 Telemedicine "Delivery of health care services, where distance is an important factor, by all health care professionals using information and communication technology for the exchange of valid information for diagnosis, treatment and prevention of disease and injury, research and evaluation, and for the continuing education of health care providers, all to advance the health of individuals and their communities."
- 2) Guideline No. 1.1.2 Telehealth "Delivery and facilitation of health and health-related services, including medical care, provider and patient education, health information services, and self-care through telecommunications and digital communication technologies."
- 3) Guideline No.1.1.3 Registered Medical Practitioner (RMP): 'A Registered Medical Practitioner [RMP] is a person registered on the State Medical Register or Indian Medical Register under the Indian Medical Council Act 1956' [IMC Act, 1956].
- 4) Guideline No.1.2 - Exceptions: Specifically excludes the following from its scope:
 - a) Specifications for hardware or software, infrastructure development & maintenance;
 - b) The data management system involved; standards and interoperability;
 - c) Use of digital technology to perform surgical or invasive procedures remotely;
 - d) Other aspects of telehealth such as research and evaluation and continuing education of health workers;
 - e) Not providing consultation outside the jurisdiction of India.
- 5) Guideline No. 1.3.1 - Registered Medical Practitioners are entitled to provide telemedicine consultations to patients from any part of India.

³⁰ ISRO Telemedicine Initiative, "Telemedicine & Law - An Indian Perspective | IIPRD Blog - Intellectual Property Discussions."

³¹ Ibid.

³² Ibid.

- 6) Guideline No.1.3.3 – Establish certain prerequisites on the part of the Board of Governors and RMP, as follows:
 - a) An online program is developed and provided by the Board of Governors replacing the Medical Council of India.
 - b) All registered medical practitioners wishing to provide online consultations must complete the mandatory online courses within 3 years of notification.

Undertaking and fulfilling the course requirements as mentioned above, is essential before practicing telemedicine consulting in India. Tech mode of practicing telemedicine that can be used:

- 1) Video (Telemedicine Facilities, Apps, Video on chat platforms, Skype/Face time, etc.);
- 2) Audio (Phone, VOIP, Apps, etc.);
- 3) Text Based: Telemedicine chat based applications (Dedicated telemedicine smartphone apps, Websites, other internet based systems, etc.); or General messaging/text/chat platforms (WhatsApp, Google Hangouts, Facebook Messenger, etc.); or Asynchronous (email/Fax, etc.).

The patient details that will be provided and collected by RMP are as follows: Name, Age, Address, Email number, Telephone number, Registered ID or other identification deemed appropriate. The details of the RMP that will be given to the patient are as follows:

- 1) The RMP must inform the patient of its qualifications;
- 2) The RMP must display the registration number assigned to him by the State Medical Council/MCI, on prescriptions, websites, electronic communications (WhatsApp/email, etc.) and receipts, etc. given to the patient.
- 3) Guideline No. 3.4 – Patient consent for telemedicine consultation is mandatory, in the form of email, text or audio/video message. Consent can be of 2 types:
 - a) Implied – If the patient initiates a telemedicine service then consent is implied.
 - b) Explicit – An explicit consent is given when the RMP, health workers and caregivers initiate telemedicine services. Prior to making a professional judgment, the RMP shall collect and record adequate medical information about the patient's condition; all records, such as case histories, investigative reports, pictures, etc.

When there is a breach of contractual obligations between the telemedicine provider and the patient then a civil lawsuit arises. That if there is a violation of obligations caused by negligence to do something then it is negligence. Regarding the doctor-patient relationship, there must be a contract that must be expressed or implied between the doctor and the patient which means that the patient must with the consent and knowingly take the doctor's assistance and the doctor accepts that consent. However, the line becomes unclear in telemedicine, when determining whether a doctor-patient relationship can exist online or via email. The doctor-patient

relationship has not been examined judicially or legislatively extensively in India, except as far as privacy and confidentiality requirements are concerned.³³

In terms of liability in Criminal negligence, the provision for criminal offenses is the Indian Penal Code, 1860 (IPC). Common lawsuits faced by doctors and such service providers cause death by negligence (Article 304-A of the Indian Penal Code [IPC]), endanger the life or personal safety of another person (Article 336 IPC), cause injury to acts that endanger the life or personal safety of another person others (Article 337 IPC) and cause serious injury due to actions that endanger the life or personal safety of others (Article 338 IPC). Penalties include imprisonment as well as fines under the relevant section.³⁴

Regarding vicarious liability, In the provision of eHealth services such as telemedicine where there is an employer-employee relationship, the employer can be sued for the principle of representative responsibility if deemed responsible for the actions and omissions of the employee arising during his employment. The principle of representative responsibility does not apply to criminal prosecution. In representative relationships between doctors or other healthcare providers and hospitals, or equivalent institutions should be concluded for (e.g. in the case of errors occurring due to communication or organizational breakdowns during telemedicine applications) the main principles of organizational responsibility will apply. The Indian Consumer Protection Act (CPA) allows consumers to claim compensation from service providers if there is a deficiency in the services provided. Consumers can make claims for defective products and unfair trade practices. Consumer forums have been set up at the district, state and national levels for these items. Supreme Court in Indian Medical Association case versus V.P. Shantha and others argue that medical services will fall within the scope of the CPA, provided that patients are charged for the services. One important element of the claim is payment for services, as CPA does not include services provided for free. Discipline control by Indian Medical Council.³⁵

A patient has the right to lodge a complaint with the relevant state medical board against a doctor for professional misconduct. If the complaint against the doctor has not been decided by the state medical board within 6 months from the date of receipt of the complaint, the Medical Council of India (MCI) may, on its own or at the request of the patient, request the state medical board to decide on the complaint or refer it to the MCI Ethics Committee. Consumers aggrieved by a state medical board decision also have the right to appeal to MCI within 60 days from the date of the order passed by the state medical board.³⁶

The Supreme Court of the Indian Medical Association has settled disputes regarding the application of the Consumer Protection Act, 1986 to persons engaged in the medical profession either as private practitioners or as government doctors working in government hospitals or pharmacies. The law also stipulates that a patient who is a 'consumer' in the sense of the law must be compensated for the loss or injury he suffered due to the negligence of the doctor by applying the same tests as applied in the act of redress for his negligence.³⁷

3.2 The Concept of Proper Telemedicine Arrangement in Providing Health

³³ Ibid.

³⁴ Ibid.

³⁵ Ibid.

³⁶ Ibid.

³⁷ Ibid.

Services Based on the Principle of Legal Certainty in Indonesia

A prosperous and just society can only be realized if the existing legal rules can be applied and enforced properly as has been done in developed and modern countries. Judging from its function, the law is a tool to maintain public order. This legal function is needed in every society, including those who are developing. Law as a social rule cannot be separated from the values that apply in a society, it can even be said that the law is a reflection of the values that apply in society.³⁸

To provide legal protection and certainty to recipients of health services, doctors, and dentists, it is necessary to have a set of regulations regarding the implementation of medical practice with the issuance of Act Number 29 of 2004 concerning Medical Practice. After Law No. 29 of 2004 was issued, the aim was to realize medical practice based on scientific values, benefits, justice, humanity, balance and protection of doctors and patients as well as patient safety. According to the Medical Practice Act, the regulation of medical practice aims to :

1. Provide protection to patients
2. Maintain and improve the quality of medical services provided by doctors and dentists
3. Provide legal certainty to the public receiving health services (patients)

Based on the description above, it can be concluded that legal development efforts in the implementation of telemedicine services are of course to fill the existing legal vacuum, which was initially motivated by changes in society that encourage the creation of legal changes. This of course must be accompanied by efforts to find the right legal concept in the implementation of telemedicine, one of which is through a comparison of laws in several countries, including Malaysia and India..

The implementation of telemedicine in Malaysia and India in the process of finding the ideal concept in Indonesia must be in line with the Legal System Theory proposed by Lawrence M. Friedmann which consists of: Legal Substances, Structure, and Legal Culture. , and the implementation of telemedicine must be based on the concept of the Indonesian legal state adhering to the Pancasila philosophy, that everyone has the right to live and defend their lives. This means that it is based on the belief of the Indonesian people, that life does not belong to humans but is a gift from God Almighty that must be protected, respected by everyone, and even must be protected by the Government and the State. Telemedicine is one of the main outcomes of the development of the health sector in the digital field. According to the World Health Organization (WHO) there are 4 (four) things that underlie the existence of telemedicine, namely:³⁹

1. Aims to support clinical care.

³⁸ Mochtar Kusumaatmadja, *Fungsi Dan Perkembangan Hukum Dalam Pembangunan Nasional* (Lembaga Penelitian Hukum dan Kriminologi, Fakultas Hukum, Universitas ..., 1970). According to Mochtar Kusumaatmadja: "Law has a function as a tool to maintain order in society. Given its function, the nature of the law is basically conservative. This means that the law is to maintain and maintain what has been achieved. Such a function is needed in every society, including those who are developing because even here there are results that must be preserved, protected and secured".

³⁹ Ahmad Efendi, "Mengenal Telemedicine Beserta Kelebihan Dan Kekurangannya," 2021, <https://tirto.id/mengenal-telemedicine-beserta-kelebihan-dan-kekurangannya-fsnL>.

2. To be a solution to the problem of distance and geography in health services.
3. Innovation using the latest information technology.
4. Improving the quality of life and public health.

Based on the description above, it can be concluded that in Indonesia the use of telemedicine is considered to be able to overcome a number of challenges that have been hampering equitable access to health, such as: uneven distribution of health workers, geographical problems, and the lack of health facilities in certain areas. Although there are still pros and cons to this feature, telemedicine is an inevitable development of telemedicine. Regulations from the side of doctors and users are still being discussed, to find a middle way that can benefit both parties. In the future, the use of telemedicine services will continue to be designed not to replace visits to doctors, but as a companion to treatment that is getting better, more efficient, and of course appropriate.⁴⁰

This condition is of course in line with the Legal System Theory proposed by Lawrence M. Friedman, which if grouped as follows:

1. Substances:
Regulation of the Minister of Health of the Republic of Indonesia No. 20 of 2019 concerning the Implementation of Telemedicine Services Between Health Service Facilities must be revised regarding the form of the relationship between doctors and patients online on the validity of therapeutic agreements, so that it becomes clear what indicators are used for the implementation of online health services. Telemedicine services as part of technological progress are indeed disruptive, therefore regulations are needed to ensure the development of telemedicine services in accordance with the goals and noble values of medical ethics based on KODEKI, and the Doctor's Oath.
2. Institutional Structure:
Basically, telemedicine is a form of innovation in health services that is able to facilitate the community. This innovation is able to help patients use their time more efficiently so they no longer need to come to the hospital for consultations. Communication about patient complaints to doctors, providing disease diagnoses from doctors to patients, then providing management advice from doctors to patients. The presence of Telemedicine is expected to be better developed with various features that can assist doctors in making accurate diagnoses, such as: recording heart rate, blood pressure, and various other things. It is necessary to make a feature to replace doctor's visits, but as a treatment companion that is more efficient, better, and faster. The government, IDI, and MKEK are expected to support and oversee the development of this telemedicine service in a good direction, and cooperate with each other in the audit and evaluation of telemedicine services in Indonesia.
3. Legal Culture:

⁴⁰ Ibid.

Although this health service is quite well known and has been widely used in foreign countries, in Indonesia itself this service is still not widely used. In Indonesia, the most frequently used telemedicine services are: text conversations, voice calls, and video calls. In practice, this telemedical service is carried out in real time or requires the presence of both parties at the same time. In addition, telemedical services also require a liaison media that intermediaries between patients and doctors such as the internet and hardware (computers and mobile phones). Telemedicine allows the presence of health workers at home, even though they met virtually before, doctors often came to patients' homes. Telemedicine, which is increasingly widely used, is facing irregularities, uncertainties and is still in a changing process, therefore, telemedicine needs to continue to be developed in order to overcome the obstacles and shortcomings of the use of telemedicine technology for the community so that it can protect the interests of the community considering the many negative impacts that can occur due to the natural law of the media. With the existence of telemedicine technology created by humans, the technology affects human life.

Some of the things that are also legal issues in the use of telemedicine in the implementation of medical practice are regarding Standard Operating Procedures, licensing, accreditation of telemedicine providers, privacy and confidentiality of patient electronic medical records, accountability in case of malpractice, and jurisdictional authority on cross-border patients. The law regarding the use of telemedicine needs to be made specifically because the legal norms in various existing regulations have not been able to regulate and follow the development of legal issues. Making regulations on telemedicine needs to pay attention to the legal principles of telemedicine while still paying attention to religious and social values in society. Basically, with adequate counseling or information from the doctor, the patient or his family can assess every step the doctor takes. Through informed consent, it is necessary to pay attention to and it is important that it is provided by the doctor and fully understood by the patient/family so that not every disappointment from the results of medical services using telemedicine becomes a case of malpractice.⁴¹

4. Conclusion

Normative legal certainty is when a regulation is made and promulgated with certainty because it regulates clearly and logically. It is clear in the sense that it does not cause doubt (multi-interpretation) and is logical. It is clear in the sense that it becomes a norm system with other norms so that it does not clash or cause norm conflicts. Associated with the above problems, there has been a legal uncertainty in the regulation of telemedicine. The absence of a special Act that regulates telemedicine, and the current Medical Practice Act does not regulate the implementation of telemedicine in Indonesia, and without legal certainty this will certainly have an impact on legal protection, both legal protection for doctors and legal protection for patients. and there are several aspects that cause conflicts of norms in the current relevant laws and regulations. Based on a comparative study with Malaysia and India, Malaysia already has a package of laws relating to cyberlaw such as the Telemedicine

⁴¹ Arman Anwar, "Aspek Hukum Penggunaan Telemedicine," *FIKI* 2013 1, no. 1 (2013).

Act, Communication and Multimedia Act, and the Digital Signature Act, Malaysia Act 564 Telemedicine Act 1997 is Act to regulate and control the practice of telemedicine. In India, telemedicine plays a very important role in enabling medical services to be made accessible and delivered to remote areas as well, all the more so as the concentration of medical healthcare facilities is found more in cities than in rural India, which makes up the majority of the national population. India has the Telemedicine Act 2003. The concept of proper regulation of telemedicine in the provision of health services based on the principle of legal certainty in Indonesia in the future, to fill the existing legal vacuum, which was initially motivated by changes in society that led to changes in the law. In finding the right legal concept related to the use of telemedicine in Indonesia, the law regarding the use of telemedicine needs to be made specifically because the legal norms in various existing regulations have not been able to regulate and follow the development of legal issues. Making regulations on telemedicine needs to pay attention to the legal principles of telemedicine while still paying attention to religious and social values in society.

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